



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

JUL 27 2015

Olympus Medical Systems Corporation  
% Ms. Laura Storms-Tyler  
Vice President, Regulatory Affairs & Quality Assurance  
Olympus America, Inc.  
3500 Corporate Parkway, PO Box 610  
Center Valley, PA 18034-0610

Re: K121564  
Trade/Device Name: Endoscopic Ultrasound Center EU-Y0006  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX, and ODG  
Dated (Date on orig SE ltr): September 18, 2012  
Received (Date on orig SE ltr): September 19, 2012

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of October 16, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Form

510(k) Number (if known): K121564

Device Name: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Indications for Use:

This ultrasound center is intended to be used with Olympus ultrasound endoscopes, Olympus ultrasound probes or Olympus esophageal ultrasound probes to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree, and urinary tract.

Prescription Use ☒   
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐   
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K121564

Page 1 of 1

### 1.3.1 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N		N		N	N (*3)	N (*4)
	Trans-vaginal							
	Trans-urethral	N		N		N	N (*3)	N (*4)
	Trans-esoph. (non-Card.)	N		N		N	N (*3)	N (*4)
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	N		N		N	N (*3)	N (*4)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

**Additional Comments:**

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for airways and tracheobronchial tree

\*2: Includes Power Doppler

\*3: Combination of each operating mode, B, PWD, Color Doppler and Other

\*4: 3-D Imaging, Harmonic Imaging

  
(Division Sign-Off)

Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121544

### 1.3.2 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE RU-75M-R1

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
Cardiac	Intravascular							
	Other (Specify) (*1)							
	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
Peripheral Vessel	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel.							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler

  
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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121564

### 1.3.3 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE RU-12M-R1

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							


N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler

  
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510K K121564

### 1.3.4 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-2R

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral	P						
	Trans-esoph. (non-Card.)	P						
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral Vessel	Other (Specify)							
	Peripheral vessel							
	Other (Specify)							

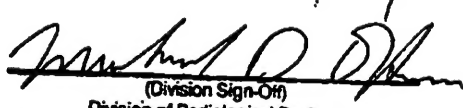
N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler

  
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Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K121504

### 1.3.5 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-3R

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral	P						
	Trans-esoph. (non-Card.)	P						
	Musculo-skeletal (Conventional)							
Cardiac	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P						
	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
Peripheral Vessel	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler



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### 1.3.6 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-S20-20R

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral	P						
	Trans-esoph. (non-Card.)	P						
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
Cardiac	Intravascular							
	Other (Specify) (*1)	P						
	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
Peripheral Vessel	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler

  
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### 1.3.7 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-G20-29R

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral	P						
	Trans-esoph. (non-Card.)	P						
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							


N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler

  
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Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K121564

### 1.3.8 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-BS20-26R

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral	P						
	Trans-esoph. (non-Card.)	P						
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

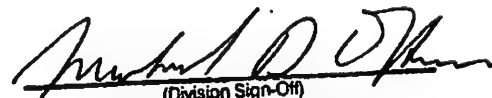
N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler

  
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Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K121564

### 1.3.9 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-S20-17S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	P						
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

**Additional Comments:**

\*1: Specification for "Other"

Gastrointestinal tract wall ;biliary duct(common bile, cystic, intrahepatic); pancreatic ducts ;  
and surrounding organs; upper airways and tracheobronchial tree.

\*2: Includes Power Doppler

  
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Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K121564

### 1.3.10 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-S30-20R

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral	P						
	Trans-esoph. (non-Card.)	P						
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler

  
(Division Sign-Off)

Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K121504

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### 1.3.12 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-DP12-25R

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						N(*3)
	Trans-vaginal							
	Trans-urethral	P						N(*3)
	Trans-esoph. (non-Card.)	P						N(*3)
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P						N(*3)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

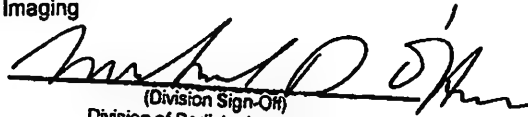
#### Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler

\*3: 3-D Imaging

  
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### 1.3.13 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-DP20-25R

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						N(*3)
	Trans-vaginal							
	Trans-urethral	P						N(*3)
	Trans-esoph. (non-Card.)	P						N(*3)
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
Cardiac	Intravascular							
	Other (Specify) (*1)	P						N(*3)
	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
Peripheral Vessel	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs,  
Intraluminal ultrasound for upper airways and tracheobronchial tree

\*2: Includes Power Doppler

\*3: 3-D Imaging

  
(Division Sign-Off)

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### 1.3.14 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC PROBE UM-DG20-31R

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						N(*3)
	Trans-vaginal							
	Trans-urethral	P						N(*3)
	Trans-esoph. (non-Card.)	P						N(*3)
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1).	P						N(*3)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

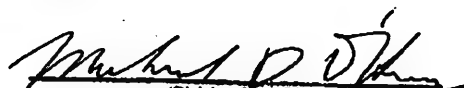
**Additional Comments:**

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs

\*2: Includes Power Doppler

\*3: 3-D Imaging

  
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### 1.3.15 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: EUS EXERA ULTRASONIC GASTROVIDEOSCOPE OLYMPUS GF TYPE UM160

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	P						
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
Cardiac	Intravascular							
	Other (Specify) (*1)	P						
	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
Peripheral Vessel	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs

\*2: Includes Power Doppler



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### 1.3.16 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: EVIS EXERA II ULTRASONIC BRONCHOFIBERVIDEOSCOPE OLYMPUS  
BF TYPE UC180F

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	P		P		P	N (*3)	N (*4)
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P		P		P	N (*3)	N (*4)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

**Additional Comments:**


\*1: Specification for "Other"

Intraluminal ultrasound for airways and tracheobronchial tree

\*2: Includes Power Doppler

\*3: Combination of each operating mode, B, PWD, Color Doppler and Other

\*4: Harmonic Imaging

  
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### 1.3.17 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC GASTROVIDEOSCOPE OLYMPUS GF TYPE UE160-AL5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	P		P		P	N (*3)	N (*4)
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P		P		P	N (*3)	N (*4)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral Vessel	Other (Specify)							
	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

**Additional Comments:**

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs

\*2: Includes Power Doppler

\*3: Combination of each operating mode, B, PWD, Color Doppler and Other

\*4: Harmonic Imaging



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### 1.3.18 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC GASTROVIDEOSCOPE OLYMPUS GF TYPE UC140P-AL5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	P		P		P	N (*3)	
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P		P		P	N (*3)	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral Vessel	Other (Specify)							
	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs

\*2: Includes Power Doppler

\*3: Combination of each operating mode, B, PWD and Color Doppler



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### 1.3.19 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: ULTRASONIC GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT140-AL5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	P		P		P	N (*3)	
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P		P		P	N (*3)	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Peripheral Vessel	Other (Specify)							
	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding organs

\*2: Includes Power Doppler

\*3: Combination of each operating mode, B, PWD and Color Doppler



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### 1.3.20 Diagnostic Ultrasound Indications For Use Format

System: ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

Transducer: EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT180

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (*2)	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	P		P		P	N (*3)	N (*4)
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) (*1)	P		P		P	N (*3)	N (*4)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments:

\*1: Specification for "Other"

Gastrointestinal tract and surrounding organs

\*2: Includes Power Doppler

\*3: Combination of each operating mode, B, PWD, Color Doppler and Other

\*4: Harmonic Imaging

  
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**510(k) SUMMARY**

April 10, 2012

**1 General Information**

- 1.1 Manufacture's Name:** OLYMPUS MEDICAL SYSTEMS CORP.  
HINODE PLANT
- Address:** 34-3 Hirai Hinode-Machi, Nishitama-gun, Tokyo,  
Japan 190-0182
- Corresponding Official:** Laura Storms-Tyler  
Olympus America Inc.
- Address:** 3500 Corporate Parkway  
PO Box 610  
Center Valley, PA 18034-0610
- Telephone:** 484-896-5688
- Facsimile:** 484-896-7128
- E-mail:** Laura.Storms-Tyler@olympus.com
- Applicant's Name:** OLYMPUS MEDICAL SYSTEMS CORP.
- Address:** 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan  
192-8507
- 1.2 Initial Distributor Name/Title/Firm:** Olympus America Inc.
- Address:** 3500 Corporate Parkway  
PO Box 610  
Center Valley, PA 18034-0610
- Telephone:** 484-896-5688



## **2 Device Identification**

■ **Device Trade Name:**

ENDOSCOPIC ULTRASOUND CENTER EU-Y0006

■ **Common Name:** Diagnostic Ultrasound System

**Regulation Number:** 892.1550 Ultrasonic pulsed doppler imaging system  
892.1560 Ultrasonic pulsed echo imaging system  
876.1500 Endoscope and Accessories  
892.1570 Diagnostic ultrasound transducer

■ **Regulatory Class:** II

■ **Product Code:** IYN, IYO, KOG, ITX

## **3 Predicate Device Information**

■ **Ultrasound System**

Subject device	Predicate device		
	Name	Manufacturer	510(k)-number
EU-Y0006 ENDOSCOPIC ULTRASOUND CENTER	XEU-M60A ENDOSCOPIC ULTRASOUND CENTER	OLYMPUS MEDICAL SYSTEMS CORP.	K063683
	HITACHI HI VISION Preirus Diagnostic Ultrasound Scanner	Hitachi Medical Corporation	K093466

## **4 Device Description**

The subject system EU-Y0006 ENDOSCOPIC ULTRASOUND CENTER combines with Ultrasound videoscopes or Ultrasound probes to make an endoscopic ultrasound imaging system that can acquire and display high-resolution and high-penetration, real-time ultrasound images of the target organs.

The subject system has modes of B, PWD, Color Doppler, Combined and Other (3-D Imaging and Harmonic Imaging).

The subject system provides measurements and calculations of distance, area, circumference, volume, time and blood velocity, providing for the storage and retrieval of

images for review and printing. The subject system enables the user to print images and record images to external recording devices.

The subject system can identify and recognize the compatible Olympus transducers and display endoscopic images in addition to ultrasound images.

The basic design, system configuration, general operation and user interface of this subject system are substantially equivalent to the predicate devices.

### **5 Indications for Use**

This ultrasound center is intended to be used with Olympus ultrasound endoscopes, Olympus ultrasound probes or Olympus esophageal ultrasound probes to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree, and urinary tract.

### **6 Comparison of Technological Characteristics**

The subject system EU-Y0006 ENDOSCOPIC ULTRASOUND CENTER is comparable with and substantially equivalent to the XEU-M60A ENDOSCOPIC ULTRASOUND CENTER (K063683) and the Diagnostic Ultrasound Scanner HITACHI HI VISION Preirus (K093466).

The subject system has same technological characteristics, key features, indications for use, and operation modes as the predicate devices.

The EU-Y0006 differs from the predicate device, XEU-M60A (K063683), in that it contains two new modes, Tissue Harmonic Imaging (THE) and Pulse Wave Doppler (PW) for ultrasound observation. However, the predicate device, Hitachi HI VISION Preirus (K093466) contains these two modes.

### **7 Summary of non-clinical testing**

The EU-Y0006 ENDOSCOPIC ULTRASOUND CENTER has been evaluated for electrical, thermal, and EMC safety. The acoustic output exposure levels will be

measured, calculated and derated following the Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and in all cases, the acoustic output does not exceed derated ISPTA of 720 mW/cm<sup>2</sup> and MI of 1.9.

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Moderate Level of Concern."

The ENDOSCOPIC ULTRASOUND CENTER EU-Y0006 is designed to comply with the following standards:

- IEC 60601-1: 1988, Amendment 1: 1991, Amendment 2: 1995
- IEC 60601-1-1: 2000
- IEC 60601-1-2: 2007
- IEC 60601-2-37: 2001, Amendment 1: 2004, Amendment 2: 2005
- IEC 60601-2-18: 1996, Amendment 1: 2000
- ISO 14971: 2007
- NEMA UD3-2004
- NEMA UD2-2004

## **8 Summary of clinical testing**

The ENDOSCOPIC ULTRASOUND CENTER EU-Y0006 did not require clinical studies to support the determination of substantial equivalence.

## **9 Conclusion**

When compared to the predicate device, the ENDOSCOPIC ULTRASOUND CENTER EU-Y0006 does not incorporate any significant changes in intended use, method of operation, or design that could affect the safety or effectiveness of the device.